Kraft Foods

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Dockets Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Registration of Food Facilities
Docket No. 02N-0276

Sir or Madam:

At Kraft Foods the safety of our products is of paramount importance, since our well-known brands are found in 99.6% of US households and sold in 150 countries around the world. Kraft is a $30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. As Kraft celebrates its centennial year, we are especially aware that the trust we have built over the last 100 years is priceless and critical to our continued success. We share the government's goal of protecting the safety of the US food supply. Furthermore, our interest in this particular proceeding is substantial, because we will be registering approximately 1000 Kraft facilities under the regulations the Food and Drug Administration (FDA) is developing.

Kraft commends the dedicated FDA personnel who are diligently attempting to implement the Bioterrorism Act in record time. We understand the pressure under which the agency's officials have been operating and the long hours they have invested and appreciate their service. We too, have devoted significant effort to improving the safety of our supply chain and to understand the impact the new regulations will have on our operations.

From our point of view, however, the stringent time constraints imposed upon this proceeding only increase the importance of incorporating into the final rule reasonable recommendations from responsible stakeholders like Kraft. We offer our practical experience and suggestions for change to improve the agency's implementation plan and not to criticize the work that has been done to date. Both government and industry are investing considerable resources in systems and procedures intended to reduce bioterrorism risks. Working together, we can assure that our efforts are as effective as possible.

Kraft recommends that FDA modify two aspects of the proposed registration rules. First, we suggest that FDA make collection of "establishment type" data mandatory, rather than voluntary, and forego collection of "FDA product code" categories for each

02N-0276 C71

registered food "manufacturer/processor" facility. The establishment type would change only rarely, but facility specific product category information would need to be updated frequently. Of much greater concern, however, is the possibility that, having gone to the expense of collecting and maintaining the product category information, FDA might rely upon the registration data base to "target communications" related to bioterrorism threats and, in so doing, fail to communicate with all affected facilities.

One manufacturer's product is another's ingredient. Ingredients are spread throughout the food supply and are stored not only at manufacturing sites but also at warehouses, retail stores and in consumer's homes. If FDA were to focus communication and investigation resources only on registered production sites for foods, all those in the supply chain that use those foods as ingredients would fail to receive potentially critical information.

Rest assured, we stand ready to answer the agency's questions about what products are made in a particular facility upon request, with the specificity necessary to facilitate effective action. However, we cannot support the proposal to build and maintain a data base by facility of arbitrarily defined "FDA product code" categories, which bear no relationship to bioterrorism risk and which could reduce communication of critical information. Thus, we are compelled to make our best effort to dissuade the agency from adopting this proposal.

Our second recommendation is related to the mechanics of gathering the registration data. While we agree that interactive registration over the Internet is likely to be efficient both for FDA and for companies registering only a few facilities, we suggest that the agency also accept transmission of electronic data files in lieu of interactive data entry. Offering companies registering a large number of facilities the option to process registration data electronically, but without using time consuming interactive data entry, will reduce entry errors and permit both the agency and larger companies to accomplish the massive registration task as efficiently as possible.

I. FDA should track Establishment Types, but not FDA Product Code Categories.

The Bioterrorism Act gives FDA discretion to gather general food category data, if the agency determines that such information is "necessary." The general food categories identified under 21 CFR 170.3 Section 170.3 are to be used, if FDA does determine that product category information for each facility is "necessary." FDA has correctly acknowledged the problems associated with use of the outdated, irrelevant 170.3 categories. Instead, the agency has tentatively decided to require submission of "FDA product code" categories concluding, we think incorrectly, that tracking FDA product code categories

> "...is necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such an incident. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected."

68 Fed. Reg. 5384. The agency's speculation that a potential threat to the food supply might be framed in terms of highly technical "FDA product code" category definitions is at best unrealistic.

The proposed categories bear no relationship to potential bioterrorism risks; thus, collecting information about the categories associated with each facility would not be useful in reducing threats to the food supply. As a practical matter, the categories are hard to work with, even for the import specialists at brokerage firms who must deal with them every day. Some categories overlap each other, yet many foods fall into gaps among the categories, so deciding which category FDA would deem correct can be quite difficult. Determining the proper category also is a struggle because the categorization scheme is in many respects counter-intuitive. Therefore, manufacturers are likely to classify similar products differently or make mistakes in reporting category classification.

Examples may help to explain the difficulty we see with the use of the "FDA product code" categories.

- If Kraft had not had prior experience importing ready to eat chocolate pudding from Canada, we would not have been familiar enough with the "FDA product codes" to know that this type of pudding is classified in the category "*bakery products, dough mixes, or icings*." We probably would have placed the product in the category described on the form as "*gelatin, rennet, pudding mixes, or pie fillings*," even though the pudding is not in mix form; or perhaps we might have selected the category described as "*chocolate and cocoa products*." Both choices would have been incorrect under the agency's product code builder scheme, for which there is a tutorial on the fda.gov web site.
- There are virtually no products on the market today labeled "imitation," yet FDA proposes "*imitation dairy products*" as a product category that must be tracked to avert risk of bioterrorism. In fact, the "imitation" designation always was solely economic--to protect consumers from spending money on products that are not "true" dairy products--and unrelated to safety or even to commonality of product composition.

- The single category 170.3(n) (3) (beverages and beverage bases) is referenced after 4 different "FDA product code" categories on the proposed registration form. We fail to see the benefit of attempting to distinguish facilities that make beverage bases, from those that make soft drinks and water, cocoa drinks, or coffee and tea. Into which category should we place a mocha coffee beverage base?
- Similarly, why does a registration need to tell FDA whether candy is made with or without chocolate? Does "without chocolate" mean without chocolate liquor or without chocolate and cocoa products?
- Why should facilities making dressings and condiments be distinguished from those making gravies and sauces? The distinction between sauces and dressings is unquestionably arbitrary and easily subject to varying interpretations.
- Likewise, is a fruit sauce a "*fruit product*" or a "*sauce*"? Banana sauce belongs in the "FDA product code" category for "*multiple food dinners, gravies, sauces, and specialties*," yet banana topping and syrup are classified in the category "*fruits and fruit products*."

Thus, under the FDA proposal, for each product (stock keeping unit or "SKU") a company makes, the company must take the time and spend the money to determine the accurate "FDA product code", and then from that detail determine the "FDA product code" category. Alternatively, the company could guess the correct category based upon the agency's descriptions on the form. The latter, more expedient, approach inevitably would lead to classification inconsistency, if not to a database full of useless information. Incidentally, Kraft alone makes over 19,000 SKUs. In short, the "FDA product code" categories simply are no more workable or useful in fostering the agency's mission of maintaining the safety of the food supply than would be the 170.3 categories FDA properly rejected.

Moreover, company officials are required to certify that all registration information is "true and accurate." The preamble tells us that FDA will consider false information to be "a materially false, fictitious, or fraudulent statement to the US government under 18 USC 1001, which subjects the person [submitting the information] to criminal penalties." 68 Fed. Reg. 5385. No one should even potentially be subject to criminal penalties for failing to discern the idiosyncrasies of the "FDA product code" system.

In the FDA training video on the proposed registration regulations, agency personnel talk about the importance of using product category information for "targeted communication," a concept that appears to be based on the faulty premise that only facilities making one or a few of the identified FDA categories would need to know about a potential threat. 68 Fed. Reg. 5384-5385. In fact, all food manufacturers need to know about potential security issues, just as all learn from recall information.

Information about potential security issues helps companies understand the mechanisms underlying various threats and prepare accordingly.

Furthermore, it is important to recognize that one food manufacturer's product is another's ingredient. Most of the proposed FDA categories are for foods that are virtually ubiquitous throughout the food supply, like cheese, dried milk products, flours, and vegetable oils. "Targeted communication" would address only primary ingredient manufacturers, not processors throughout the system that use those ingredients in other food products. Improperly targeted communication based upon the "FDA product code" categories could hinder, rather than foster, effective response to a potential threat as well as the associated FDA investigations and surveillance operations.

The agency's "targeted communication" concept also presumes that a serious threat would not need to be public. If that presumption were correct, public media would not be needed routinely in Class I recall situations.

Instead of collecting data on FDA product code categories, Kraft urges FDA to make mandatory submission of information on establishment types and type of storage for warehouses (see section 9 of the proposed registration form). This information would not change frequently, as would product categories, and might well be useful to FDA in targeting some types of communications and allocating agency inspection resources. For example, the establishment type information would make it possible for FDA to segregate manufacturing facilities from all the other types of facilities required to register. FDA also could identify easily manufacturers of higher risk products such as acidified/low acid food processors or mollusk shellfish establishments. Incidentally, FDA is unlikely to get voluntary compliance with the request for establishment and storage type information, when penalties would be imposed if this optional information were inaccurate when submitted initially or became out of date. Therefore, we suggest that establishment type data and type of storage for warehouses should be made mandatory.

Additionally, the proposed rules appropriately require submission of the emergency contact information FDA unquestionably needs for "a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency." Kraft recommends that the agency expand that section of the form, so that food companies can provide several back-ups to the identified primary emergency contact person. At our company, for example, the main security telephone number always can be used to reach the people on the Special Situations Management Team. We would like to provide that phone number in addition to all the contact information for our primary emergency contact, just in case unforeseen circumstances make back up necessary.

During investigations, FDA will not need to rely upon the establishment type and emergency contact information alone, however, for the agency also will be adopting

regulations for tracking movement of food ingredients and finished products. Thus, there is no need for the agency to stretch the registration rules to cover product category tracking information. Other provisions of the Bioterrorism Act will enable FDA to get records that would be much more useful during any investigation.

In summary, collection of "FDA product code" category data is not required by the Bioterrorism Act, is unnecessary for the accomplishment of the agency's mission, and is not useful as a practical matter. Tracking "FDA product code" categories for each facility would not improve the agency's capacity to protect the public health, but would increase the cost of the registration system and would divert resources that should be focused elsewhere. With the emergency contact information provided as part of the company's registration, FDA will have the best possible means of reaching key decision makers quickly, so proper actions can be taken immediately by people who are familiar with their company's products, systems, and distribution practices.

II. The agency's cost estimates are understated.

The agency's cost estimates are understated and based on assumptions that do not reflect typical operating practices. To research and understand the rules, any company would need far more than the one-hour FDA factored into the economic impact assessment. The proposal is 40 pages of fine print in the Federal Register. The agency's video takes another hour to watch. No time was allocated for the task of evaluating the implications of the proposed rules for current business systems or for preparing comments. When the final rules are published, assuring compliance will involve reading and understanding the final Federal Register document as well as any accompanying question and answer documents or videos. The "FDA product code" is not used by industry, so companies first will need to learn the agency's system and then will need to classify products by facility. FDA proposes to require management certification that the submission is accurate, but does not appear to have factored the time the manager needs to learn the agency's requirements into the economic analysis. No systems development costs were included. Furthermore, the actual average wage rate at Kraft for the type of personnel who would be responsible for registration activities is $75 hourly (including benefits), far more than the $33 per hour weighted average wage rate used by FDA ($25.10 per hour for ¾ hour for an administrative worker plus $56.74 per hour for ¼ hour for management personnel yields a weighted average wage rate of $33 per hour).

These inaccuracies in the economic analysis are not nearly as significant as the cost of collecting the highly questionable "FDA product code" data. Of all the information FDA proposes to collect, only the product category information would change constantly, as manufacturers move product lines to achieve optimum use of their facilities and introduce new products. At Kraft, we would need to update our registrations monthly, so tracking FDA product categories would not only be difficult initially, as the technically

correct categories for 19,000 products would need to be determined, but would require a significant ongoing investment.

FDA estimated that deleting product categories would save 15 minutes or $8.25 per facility (using the weighted average wage rate of $33 per hour), without considering the cost of keeping the registration data up to date after the information is first gathered. We estimated the ongoing cost of maintaining registrations for facilities making products for Kraft as follows:

- Approximately 400 facilities make products distributed by Kraft.
- Some change requiring review is likely to go on at 100 of the 400 facilities each month.
- We estimate it would take about 1-½ hours per facility to identify changes, evaluate implications, and, if necessary, update the registrations (in the 1-½ hours, we counted ½ hour of plant time and 1 hour of headquarters time).
- Therefore, 150 hours per month or 1800 hours per year could be needed to keep the FDA product category database up to date.
- Applying the typical industry wage rate of $75 per hour, estimated ongoing yearly costs for submitting updated product category data would be around $135,000 each year.

Even given the rough nature of these estimates, adding product categories to the required registration data would result in ongoing investments for industry and FDA together totaling millions of dollars over a few years, if not in the first year alone. If this investment would increase safety, the cost would be justified; but FDA has not identified a safety benefit nor have we been able to identify one. Moreover, processing constant minor registration changes related to changing food categories would not be a good use of FDA or industry resources. From our point of view, sound policy requires that these resources be used for more focused and productive security measures.

III. FDA should accept electronic data files as well as registration data entered interactively.

FDA could reduce the burden of collecting the information, if multi-facility registrants were able to send a single transmission containing all of the requisite data, in lieu of entering the data interactively over the Internet. The interactive Internet data entry approach is probably excellent for many small manufacturers, but is too time consuming for companies, like Kraft, that must register hundreds of facilities. Assuming the 1 hour FDA data entry estimate were correct, Kraft would need 1000 hours to enter data for our facilities. At 40 hrs per week, the task would take 25 weeks, far more than the 8 weeks provided, if only one person could be entering data interactively for a single company at

a time. Thus, we suggest that the final rule include a format for submitting electronic data files, such as XML documents, Microsoft Excel documents, or standard flat files. Additionally, we recommend that the agency make provisions for a single registrant to stop entering data and begin again another day as well as for a single registrant to enter data simultaneously from more than one desktop.

Conclusion

Americans depend upon both industry and government to assure the safety of the food supply. Deploying government and industry resources as effectively and efficiently as possible is essential. Adjusting the information collection requirements and the data transmission methods proposed for FDA facility registrations as we have suggested will enable industry and FDA to comply with Congressional directives without unnecessarily misdirecting resources that could be better used for more focused security measures.

Kraft always is ready to work with the government to protect the safety of the food supply. Please do not hesitate to contact me at (847) 646-6125, if we can provide additional information that might be helpful.

Sincerely,

Jean E. Spence

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